MAR 27 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date

12/8/2011

Manufacturer

Vatech Co., Ltd.
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Official Correspondent (U.S. Designated agent)

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Contact person: Mr. Dave Kim (davekim@mtech-inc.net)

Trade/Proprietary Name:

PCH-2500

Common Name:

Digital X-ray Imaging System

Classification Name:

System, X-Ray, Extra oral Source, Digital (21CFR 872.1800, Product code MUH, class2)

Description:

PCH-2500 is a dental digital radiographic imaging system which is available in two different image acquisition modes. Specifically designed for dental radiography of the teeth or jaws, PCH-2500 can be equipped with three dedicated sensors, each for two X-ray modalities : panoramic (Xmaru1501CF), cephalometric scan type (Xmaru2301CF) and oneshot ceph sensor type (1210SGA).

PCH-2500 offers the digital panoramic and cephalometric X-ray modality for dental radiographs. The multi platforms of PCH-2500 imaging mode provides a wide range of imaging option based on the customer's diagnostic needs.

Indication for use:

PCH-2500 is digital extra oral source x-ray system intended to take panoramic and cephalometric images of the oral and maxillofacial anatomy to provide diagnostic information for adult and pediatric patients. The device should be operated and used by dentists, x-ray technicians and other professionals licensed by the law of the state in which the device is used.

Predicate Device:

Manufacturer	: Vatech Co., Ltd
Device	: PaX-Flex3D
510(k) Number	: K102259 (Decision Date – 2/18/2011)

Substantial Equivalence:

PCH-2500 described in this 510(k) has the similar intended use and technical characteristics as PaX-Flex3D of Vatech Co., Ltd.

Characteristic	Proposed Vatech Co., Ltd. PCH-2500	Predicate Vatech Co., Ltd. PaX-Flex3D
510(k) number	-	K102259
Indications for use	PCH-2500 is digital extra oral source x-ray system intended	PaX-Flex3D is a computed tomography x-ray system intended to

	to take panoramic and cephalometric images of the oral and maxillofacial anatomy to provide diagnostic information for adult and pediatric patients. The device should be operated and used by dentists, x-ray technicians and other professionals licensed by the law of the state in which the device is used.	produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of X-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360 rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and X-ray technicians.
Performance Specification	Panoramic and cephalometric	Panoramic and cephalometric and compute tomography
Input Voltage	AC 100-120 / 200-240 V	AC 110 / 230 V
Tube Voltage	50-90 kV	50-90 kV
Tube Current	4-10 mA	4-10 mA
Focal Spot Size	0.5 mm	0.5 mm
Exposure Time	Max 20.2 s	9-24 s
Total Filtration	2.8 mmAl	2.8 mmAl
Pixel Resolution	Panoramic : 5 lp/mm	Panoramic : 5 lp/mm
	Cephalometric (scan type) 5 lp/mm :	Cephalometric (scan type) 5 lp/mm :
	Cephalometric (one shot type) 3.9 lp/mm :	
	CT – N/A	CT - 3.3 lp/mm
Pixel Size	Panoramic : 100 x 100 μm	Panoramic - 100 x 100 μm
	Cephalometric (scan type): 100 x 100 μm :	Cephalometric (scan type): 100 x 100 μm :

	Cephalometric (one shot type) 127 x 127 μm :	
	CT - N/A	CT : 150 x 150 μm/200 x 200 μm
Image Receptor	CMOS photodiode array – panoramic (Xmaru1501CF) & cephalometric (Xmaru2301CF) Amorphous silicon TFT with scintillator – Cephalometric (1210SGA)	CMOS photodiode array – panoramic (Xmaru1501CF) & cephalometric (Xmaru2301CF)

Indications for use, safety characteristics, and non-clinical performance for panoramic and cephalometric sensors (scan type) of PCH-2500 and PaX-Flex3D are similar. The primary differences are as follows: PCH-2500 lacks the cone beam CT mode. PCH-2500 offers optional solid state X-ray sensor for cephalometric mode. (The non-clinical performance and clinical consideration report for the SSXI detector, 1210SGA, are provided separately in this submission). Based on the non-clinical and clinical consideration and the outcome of an expert review of image comparisons for both devices, we can claim the substantial equivalence of PCH-2500 in comparison with PaX-Flex3D, the predicate device, in terms of safety and effectiveness.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (2001), IEC 60601-1-3 (Ed. 1, 1994), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed. 1, 1993) and IEC 60601-2-32 (Ed. 1, 1994) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

PCH-2500 also meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.

Acceptance test according to IEC 61223-3-4 and IEC 61223-3-5 was performed.

All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that PCH-2500 is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 27 2012

Vatech Co., Ltd.
Mr. Dave Kim
Official Correspondent
Mtech Group
12946 Kimberly Lane
HOUSTON TX 77079

Re: K113672
Trade/Device Name: PCH-2500
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH and MQB
Dated: February 14, 2012
Received: February 16, 2012

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K113672

Indications for Use

510(k) Number(if known):

Device Name: PCH-2500

Classification: System, X-Ray, Extraoral Source, Digital
(21 CFR 872.1800, Product code MUH, Class2)

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Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113672

Concurrence of CDRH, Office of Device Evaluation(ODE)